SECTION 2. SUMMARY AND CERTIFICATION

A. 510(K) SUMMARY

Summary of Safety and Effectiveness

In accordance with 21 CFR 807.92, the following information constitutes the Medwave, Inc. summary for the Vasotrac® APM205A System.

SUBMITTER'S NAME:	Medwave, Inc.
ADDRESS:	4382 Round Lake Road West St. Paul, MN 55112
CONTACT PERSON:	Donna R. Lunak
TELEPHONE NUMBER:	651-639-1227
FAX NUMBER:	651-639-1338
DATE OF SUBMISSION:	03/30/01

1. Identification of device

Proprietary Name: Vasotrac® APM205A
Common Name: Non-invasive blood pressure measurement system
Classification Status: Class II per regulations 870.1130 Product Codes

2. Equivalent devices

Medwave, Inc. believes the Vasotrac® APM205A System is substantially equivalent to Medwave, Inc. Vasotrac® System (K950249).

3. Description of the Device

The Vasotrac APM205A System is a non-invasive blood pressure monitor that uses a pressure sensor placed directly on top of the radial artery. This sensor is noninvasive and eliminates the need for an occlusive inflatable cuff. This device is intended to be used on patients by medical personnel to continually monitor systolic, diastolic and mean blood pressure, and pulse rate.

The Vasotrac APM205A System uses a patented "sweep technique" which applies a varying force on the radial artery. The counterpressure in the artery produces a signal which is digitized and used to calculate blood pressure parameters.

The sensor measures the pulse at the point of maximum energy transfer; the wave shapes are analyzed by Medwave's proprietary algorithms. Parameters are

Description of the Device (continued)

extracted from the waveforms and a set of coefficients are applied to them yielding systolic, mean, and diastolic pressures approximately every 15 heart beats. These algorithms have been tested and validated in clinical studies by synchronized comparisons to arterial line pressure waveforms.

Patient pressures can be monitored visually by viewing the screen and audibly entering limits into the Vasotrac APM205A System alarm menu. Patient measurements above or below the limits will be automatically brought to the attention of the caregiver through these visual and audible alarms. A Start/Stop key provides the operator with an option to cancel operation at anytime.

4. Intended Use

The Vasotrac® APM205A System is a non-invasive blood pressure monitor, which uses a pressure sensor placed on the wrist over the radial artery. This device is intended to be used on patients by trained medical personnel to continually monitor systolic, diastolic and mean blood pressure and pulse rate. The information from this device is intended to guide clinicians in the therapeutic management of their patients by: providing accurate and frequently updated blood pressure information in a safe, non-invasive, easily obtained, and comfortable manner.

5. Technological characteristics, comparison to predicate device.

Like the predicate device, the Vasotrac® APM205A System is a non-invasive blood pressure monitor, which uses a pressure sensor placed on the wrist over the radial artery. This device is intended to be used on patients by trained medical personnel to continually monitor systolic, diastolic and mean blood pressure and pulse rate. The information from this device is intended to guide clinicians in the therapeutic management of their patients by: providing accurate and frequently updated blood pressure information in a safe, non-invasive, easily obtained, and comfortable manner. Both the devices measure the diastolic, systolic blood pressure and pulse rate from the wrist using oscillometric methods. Both the devices are microcomputer controlled.

Like the Vasotrac® System (K950249), the Vasotrac® APM205A System have a memory function that retains approximately 900 readings.

Like the Vasotrac® System (K950249), the Vasotrac® APM205A System display systolic, diastolic blood pressures ranging from 40 and 240 mmHg. Both systems have a blood pressure measurement accuracy of a mean difference of $\pm$ 5mmHg or less with a standard deviation of 8mmHg or less. The pulse measurement range is the same for both the Vasotrac® System (K950249) and the Vasotrac APM205A System, from 40 – 200 bpm. The accuracy of the pulse measurements are $\pm$ 5 bpm or 10% of the measured pulse frequency.

(Supported by study results in the supporting Clinical Data on file at Medwave, Inc.)

Technological characteristics, comparison to predicate device (continued)

Both Vasotrac® System (K950249) and the Vasotrac® APM205A System utilize the application of pressure to the artery (by the sensor); the counter pressure in the artery produces a pressure waveform. When maximum amplitude is achieved, mean blood pressure is calculated. The Vasotrac® System (K950249) and the Vasotrac® APM205A System use a unique "sweep" technique for applying pressure to a the radial artery: downward pressure is applied by the sensor to the radial artery at a rate of ~10mmHg per heart beat increasing as the beat amplitude increases and decreasing rapidly when the beat amplitude begins to decrease. A curve fit is made using the amplitude of each beat versus the hold down pressure to form the bell shaped curve. This curve fit is used to determine the true peak that might occur between pulses as well as to filter out small variations due to artifacts or aberrancies.

Both the Vasotrac® System (K950249) and the Vasotrac® APM205A System utilize Medwave's proprietary algorithms in analyzing the pressure waveforms to calculate the systolic, mean and diastolic readings. Parameters are extracted from the waveforms and a set of coefficients is applied to them, yielding systolic, mean and diastolic pressures. The algorithms have been tested against intra arterial line pressure waveforms and proven to meet industry standards set by the American Medical Instrumentation (AAMI), mean difference of + 5mmHg or less with a standard deviation of 8mmHg or less.

(Supported by study results in the Clinical Data on file at Medwave, Inc.)

The Vasotrac System (K950249), as theVasotrac® APM205A System, has a power switch and a LCD display. The operating environment of $10^0C - 40^0C$ and 10% to 90% relative humidity. Any minor differences in the appearance, technology, or manufacture of the predicate device and the Vasotrac® APM205A System do not raise any new questions of safety or effectiveness. Associated risks posed by the Vasotrac® APM205A System are thought to be no more than those of well-designed automated cuff-based noninvasive blood pressure devices currently marketed in the interstate commerce are. Both the device and the sensor have been designed to minimize the risk to patients from burns, excessive pressure or sensor failure caused by either normal device use by patient and/or clinical abuse.

6. Discussion of performance testing.

An extensive collection of tests has been conducted and successfully completed. Summary follows:

Requirements	ANSI/AAMI SP10-1992 American National Standards for Electronic or Automated Sphygmomanometers	UL2601	Center For Devices And Radiological Health Noninvasive Blood Pressure Monitor Guidance Document	Other As Listed
Device Labeling	X	X	X	---------- --------
Outer Container Labeling	X	X	X	---------- --------
Information Manual	X	X	X	---------- --------
Component Labeling	X	X	X	---------- --------
Power System Labeling	X	----	X	---------- ---------
Storage Conditions – 20^0C (-40^0F) – 50^0C (122^0F)	X	----	----------	---------- ---------
Operating Temperature Conditions 10^0C (50^0F) – 40^0C (104^0F)	X	----	----------	---------- ---------
Operating Humidity Conditions 15 – 90 percent (noncondensing)	X	----	----------	---------- ---------
Operating Range in Altitude Conditions -170 to 1700 meters (-500 to 5000 feet), referenced to sea level	X	----	----------	---------- ---------
Vibration and Shock	----------	---------- --	----------	NSTA
Voltage Range	N/A	N/A	N/A	N/A
Life test minimum of 10,000 full scale cycles	X	---------- ---	----------	---------- -----
Maximum cuff pressure	N/A	N/A	N/A	N/A
Cuff deflation	N/A	N/A	N/A	N/A
Electrical safety	----------	X	----------	IEC601
Conductive components	----------	X	----------	---------- -----
Pressure indicator accuracy	X	---------- ---	----------	---------- -----
Overall system efficacy	X	---------- -	----------	---------- -----
Auscultatory method as the reference standard	N/A	N/A	N/A	N/A
Intraarterial method as the reference standard	X	---------- ---	----------	---------- -----
Battery indicator	N/A	---------- ---	----------	---------- -----

Requirements	ANSI/AAMI SP10-1992 American National Standards for Electronic or Automated Sphygmomanometers	UL2601	Center For Devices And Radiological Health Noninvasive Blood Pressure Monitor Guidance Document	Other As Listed
Requirements for devices with manual inflation	N/A	N/A	N/A	N/A
Comparison Testing	N/A	N/A	N/A	N/A
Foreign Standards	N/A	N/A	N/A	N/A
Software Testing	----------	---------- ---	----------	Medwave 795-0000
Electromagnetic Compatibility	----------	X	----------	---------- ----------
Biocompatibility	----------	----	X	---------- ----------
Sterilization	N/A	N/A	N/A	N/A
Packaging	N/A	N/A	N/A	N/A
Shelf Life	N/A	N/A	N/A	N/A

6. Conclusion

Based on extensive performance testing and a comparison to the predicate device, it is the conclusion of Medwave, Inc. that Vasotrac® APM205A System is substantially equivalent to devices already on the market (cleared by the 510(k) process) and presents no new concerns about safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 31 2001

Mr. Tim O' Malley
President
Medwave, Inc.
4382 Round Lake Road West
Arden Hills, MN 55112

Re: K011152
Trade Name: Vasotrac® APM205A Noninvasive Blood Pressure Measurement System
Regulation Number: 870.1130
Regulation Class: II (two)
Product Code: DXN
Dated: April 12, 2001
Received: April 16, 2001

Dear Mr. O'Malley:

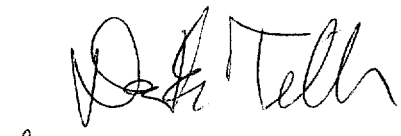
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

B. INDICATIONS FOR USE

510(k) Number K011152

Device Name:

Vasotrac® APM205A System

Indications for Use:

The Vasotrac® APM205A is a non-invasive blood pressure monitor which uses a pressure sensor placed on the wrist over the radial artery. This device is intended to be used on patients by trained medical personnel to continually monitor systolic, diastolic and mean blood pressure and pulse rate. The information from this device is intended to guide clinicians in the therapeutic management of their patients by: providing accurate and frequently updated blood pressure information in a safe, non-invasive, easily obtained, and comfortable manner.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Vascular & Respiratory Devices
K011152

Prescription Use ✓ OR Over the Counter Use_____
(Per 21 CFR 801.109)